

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

GEOFFREY PESCE

Plaintiff,

v.

KEVIN F. COPPINGER, in his official
capacity as Essex County Sheriff, AARON
EASTMAN, in his official capacity as
Superintendent of the Essex County House
of Corrections – Middleton,

Defendants

C.A. No. 18-cv-11972-DJC

**BRIEF OF THE PUBLIC HEALTH
SCHOLARS AS *AMICI CURIAE* IN
SUPPORT OF PLAINTIFF'S MOTION
FOR TEMPORARY RESTRAINING
ORDER AND PRELIMINARY
INJUNCTION**

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INTERESTS OF AMICI CURIAE

Amici curiae are professors of public health and degree candidates in graduate programs in public health at the Johns Hopkins Bloomberg School of Public Health. They have extensive knowledge of the research into addiction treatment and experience in the field of public health. As scholars in the field of public health, *amici* seek to provide the Court with their expertise and knowledge regarding the evidence supporting the treatment of opioid use disorder (OUD) with medications for opioid use disorder (MOUD, sometimes referred to as medication assisted therapy or MAT). *Amici's* perspective will provide the Court with a deeper and more comprehensive understanding of the state of research into treatment of OUD and the relative benefits and risks associated with methadone and MOUDs.

Amici curiae are:

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Brendan Saloner, PhD, Assistant Professor in Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health and the author of multiple scholarly publications on addiction treatment.

Colleen Barry, PhD, Professor in and Chair of the Department of Health Policy and Management at the Johns Hopkins Bloomberg School of Public Health. She is also the founding Co-Director of the Center for Mental Health and Addiction Policy Research.

Noa Krawczyk, PhD Candidate at the Johns Hopkins Bloomberg School of Public Health. Jenny Wen and Jia Ahmad, MPH Candidates at the Johns Hopkins Bloomberg School of Public Health.

The views expressed here are those of the *amici curiae* and do not necessarily reflect the views of Johns Hopkins University or Johns Hopkins Bloomberg School of Public Health.

SUMMARY OF THE ARGUMENT

Plaintiff is currently in a successful OUD treatment program and is receiving methadone. Defendants propose to end this treatment, force withdrawal from methadone, and provide depot naltrexone shortly before the plaintiff is set to be released. Defendants base their proposal in part on an inaccurate description of the nature of, and risks associated with, methadone for OUD and the scientific consensus on access to methadone for OUD.

Methadone is an approved treatment for OUD, with the Substance Abuse Mental Health Services Administration (SAMHSA) stating in 2018 that “methadone treatment has by far the largest, oldest evidence base of all treatment approaches to opioid addiction.”¹ The agency stated that “large multisite longitudinal studies from the world over support methadone maintenance’s effectiveness” and that methadone treatment is associated with “reduced risk of overdose-related deaths,” “reduced risk of HIV and hepatitis C infection,” and “reduced criminal behavior.”² Treatment with methadone is not another form of addiction; rather it helps patients manage their OUD. Although methadone is not without side effects, the scientific consensus is that the

¹ SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN., MEDICATIONS FOR OPIOID DISORDER 1-5 (2018).

² *Id.*

benefits of methadone greatly outweigh the associated risks for patients with OUD. Moreover, the defendants overstate the risks associated with methadone treatment for OUD.

In contrast, providing exclusively depot naltrexone following forced withdrawal from treatment with methadone, as defendants propose, is not recommended by medical or scientific authorities. The scientific consensus supports offering all types of MOUD to patients and using the type of MOUD that is most conducive for the individual patient. It does not support forced withdrawal from treatment with methadone or buprenorphine to allow for treatment with depot naltrexone. Doing so exposes patients to significant and unnecessary pain and risk of injury or death, and can significantly disrupt effective treatment. Moreover, the evidence supporting methadone treatment is more extensive than the evidence for depot naltrexone.

ARGUMENT

I. DEFENDANTS MISCHARACTERIZE METHADONE TREATMENT

A. Methadone Treatment Is Not A New or Continued Addiction

Defendants claim that utilizing methadone treatment simply continues the user's addiction because methadone creates the same addictive effects as heroin. This is incorrect. Treatment with methadone is not addiction. It is not simply switching to another dangerous drug. Methadone is an opioid; however, there are significant differences between methadone and other opioids such as heroin. Because its long half-life minimizes variations in blood levels,³ methadone normalizes chemical disruptions experienced by a person with opioid addiction, helping patients return to normal functioning, and decreasing drug seeking.⁴ When used for

³ See Hilary Smith Connery, *Medication-Assisted Treatment of Opioid Use Disorder: Review Of The Evidence And Future Directions*, 23 HARV. REV. PSYCHIATRY 63, 63 (2015) <https://pdfs.semanticscholar.org/959c/e3caf1fe3bed9da973bc8a1530a9ead497b1.pdf>

⁴ Thomas R. Kosten & Tony P. George, *The Neurobiology Of Opioid Dependence: Implications For Treatment, Science & Practice Perspectives*, 1 ADDICTION SCI. & CLINICAL PRACTICE 13 (2002), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054/#__sec2title.

OD, methadone does not cause euphoria.⁵ Most importantly, methadone treatment improves health and safety by significantly reducing the risk of overdose and death.⁶ In short, decades of research have shown that long-term methadone treatment is extremely effective in treating opioid addiction, reducing illicit opioid use and overdose, and improving health and functioning.⁷

In fact, FDA has approved methadone as a safe and effective treatment for OD,⁸ and organizations such as the National Institutes of Health,⁹ the Centers for Disease Control and Prevention,¹⁰ World Health Organization,¹¹ and the American Society for Addiction Medicine¹² recommend its use. As with all opioids, methadone causes physical dependence, which means that stopping the medication causes a physical withdrawal syndrome. This physiological phenomenon is not addiction. In the fall of 2017, FDA Commissioner Scott Gottlieb made this very point while testifying before Congress about the use of medications for addiction treatment:

Addiction requires the continued use of opioids despite harmful consequences. Addiction involves a psychological craving above and beyond a physical dependence. Someone who neglects his family, has trouble holding a job, or commits crimes to obtain opioids has an addiction. But someone who is physically dependent on opioids as a result of the treatment of pain but who is not craving more or harming themselves or others is not addicted. The same principle applies to medications used to treat opioid addiction. Someone who requires long-term treatment for opioid addiction with medications—including those that cause a

⁵ James Bell and Deborah Zador, *A Risk-Benefit Analysis of Methadone Maintenance Treatment*, 22 DRUG SAFETY 179, 185 (2000).

⁶ Luis Sordo et al., *Mortality Risk During And After Opioid Substitution Treatment: Systematic Review And Meta-Analysis Of Cohort Studies*, BMJ, Apr. 29, 2017, <https://www.bmj.com/content/357/bmj.j1550>.

⁷ See SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN, *supra* note 1.

⁸ *Information About Medication-Assisted Treatment (MAT)*, U.S. FOOD & DRUG ADMIN. (Oct. 3, 2018), <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm600092.htm>.

⁹ *Effective Treatments for Opioid Addiction*, NAT'L HEALTH INST., NAT'L INST. ON DRUG ABUSE, <https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction>. (last visited Oct. 31, 2018).

¹⁰ See *Learn About Addiction Treatment*, CTR. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/rxawareness/treatment/index.html>. (last visited Nov. 1, 2018).

¹¹ WORLD HEALTH ORG., GUIDELINES FOR THE PSYCHOSOCIALLY ASSISTED PHARMACOLOGICAL TREATMENT OF OPIOID DEPENDENCE 12 (2009).

¹² AMERICAN SOCIETY OF ADDICTION MEDICINE (ASAM) NATIONAL PRACTICE GUIDELINE FOR THE USE OF MEDICATIONS IN THE TREATMENT OF ADDICTION INVOLVING OPIOID USE 29-31 (2015).

physical dependence—is not addicted to those medications. ... We should not consider people who hold jobs, re-engage with their families, and regain control over their lives through treatment that uses medications to be addicted. Rather, we should consider them to be role models in the fight against the opioid epidemic.¹³

B. OUD Treatment With Methadone Is Safe

Defendants inaccurately paint methadone as a dangerous drug with fatal side effects. For example, defendants incorrectly cite a CDC report to claim that methadone is responsible for a quarter of opioid-related deaths. This is incorrect. The CDC report stated that methadone was responsible for one quarter of *prescription* opioid-related deaths.¹⁴ In fact, the main cause of opioid-related deaths is fentanyl, not prescription opioids like methadone.¹⁵ The Massachusetts Department of Health states that fentanyl is present in more than 89% of opioid-related deaths, whereas prescription opioids are only present in less than 20% of opioid-related deaths.¹⁶ Based on the CDC study, we would expect methadone to be present in a quarter of these overdoses, or less than 5% of opioid overdoses overall. Further, the same report also stated that methadone-related overdoses have declined 39% since their peak in 2006-2007.¹⁷

Moreover, most methadone-related overdoses are related to methadone use for chronic pain, not its use for addiction treatment.¹⁸ Indeed, the evidence is clear that restricting access to

¹³ Scott Gottlieb, Commissioner, Food & Drug Admin., Testimony before The House Committee on Energy and Commerce: Federal Efforts to Combat the Opioid Crisis: A Status Update on CARA and Other Initiatives (Oct. 25, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm582031.htm>).

¹⁴ Mark Faul et al., *Methadone Prescribing and Overdose and the Association with Medicaid Preferred Drug List Policies — United States, 2007 – 2014*, CTR. FOR DISEASE CONTROL AND PREVENTION, MORBIDITY AND MORTALITY WEEKLY REP., Mar. 31, 2017, <https://www.cdc.gov/mmwr/volumes/66/wr/mm6612a2.htm>.

¹⁵ Puja Seth et al., *Overdose Deaths Involving Opioids, Cocaine, and Psychostimulants — United States, 2015 – 2016*, CTR. FOR DISEASE CONTROL AND PREVENTION, MORBIDITY AND MORTALITY WEEKLY REP., Mar. 30, 2018, <https://www.cdc.gov/mmwr/volumes/67/wr/mm6712a1.htm>.

¹⁶ MASS. DEP'T OF PUB. HEALTH: OPIOID-RELATED OVERDOSE DEATHS AMONG MASS. RESIDENTS 3 (2018), https://www.mass.gov/files/documents/2018/08/24/Opioid-related%20Overdose%20Deaths%20among%20MA%20Residents%20-%20August%202018_0.pdf).

¹⁷ Faul, *supra* note 14.

¹⁸ Christopher M. Jones et al., *Trends in Methadone Distribution for Pain Treatment, Methadone Diversion, and Overdose Deaths — United States, 2002–2014*, CTR. FOR DISEASE CONTROL AND PREVENTION, MORBIDITY AND MORTALITY WEEKLY REP., Jul. 8, 2017, <https://www.cdc.gov/mmwr/volumes/65/wr/>

treatment with methadone will not reduce mortality rates. In fact, studies of both the general population and of people in detention demonstrate that engagement in treatment with methadone decreases the risk of death.¹⁹

Defendants also overstate the risks posed by methadone in a prison setting. Defendants note that methadone can be fatal when combined with alcohol or other sedatives, but that combination is unlikely to occur in a detention center. Although methadone may cause QT prolongation—a heart rhythm change—a clinician can monitor this side effect.²⁰ QT prolongation itself is not symptomatic; a small percentage of people with QT prolongation can experience a serious heart arrhythmia. There are a variety of medications that cause QT prolongation, including antiarrhythmics, antihistamines, antimicrobials, and psychiatric medications; defendants note that Zofran, a drug that also can cause QT prolongation, is currently in use at this detention facility.²¹ Finally, defendants state that methadone can cause serotonin syndrome without explaining that it is an exceptionally rare side effect and is unlikely to occur unless methadone is paired with other medications, such as anti-depressants.²² Even if users were to experience these side effects, their mere existence is not a reason to withhold necessary treatment for a medical disorder.

mm6526a2.htm.

¹⁹ Sordo, *supra* note 6; Marc R. Larochelle et al., *Medication for Opioid Use Disorder After Nonfatal Opioid Overdose and Association With Mortality*, ANN INTERN MED., Aug. 7, 2018, <http://annals.org/aim/fullarticle/2684924/medication-opioid-use-disorder-after-nonfatal-opioid-overdose-association-mortality>.

²⁰ *No Evidence to Support QTC-Interval Screening in Methadone Maintenance Treatment: Cochrane Review*, ADDICTION TREATMENT F., (July 19, 2013), <http://atforum.com/2013/07/no-evidence-to-support-qtc-interval-screening-in-methadone-maintenance-treatment-cochrane-review/> (summarizing the studies supporting the use of methadone with screenings).

²¹ See Defendant Kevin F. Coppinger and Aaron Eastman's Memorandum of L. in Support of Their Opposition to Plaintiff's Motion for Temporary Restraining Order and Preliminary Injunction at 9; see also FDA Drug Safety; Communication: *New Information Regarding QT Prolongation With Ondansetron (Zofran)*, U.S. FOOD & DRUG ADMIN., (June 29, 2012), <https://www.fda.gov/Drugs/DrugSafety/ucm310190.htm>.

²² Douglas J. Weschules et al., *Actual and Potential Drug Interactions Associated with Methadone*, 9 PAIN MED. 315, 325 (2008).

These arguments obfuscate the core point that medical and scientific authorities recommend OUD treatment with methadone because the benefits of the treatment outweigh the risks.

Finally, defendants argue that there are safety reasons to ban methadone within the facility. Correctional facilities often cite concern about illicit diversion of opioid treatment medications as a reason not to provide FDA-approved treatment. However, there is ample evidence that treatment programs can be run effectively in correctional settings without appreciable problems with diversion. One such example is the Rikers' Island jail in New York City.²³

In fact, diversion of illicit opioids within correctional facilities is more likely to occur when the facilities fail to provide effective treatment. A concentration of people with untreated OUD is fertile ground for a market in illicit opioids. Evidence suggests that the presence of illicit treatment drugs in jails occurs because inmates who are struggling with opioid addiction are not able to access FDA-approved treatment behind bars.²⁴ People with opioid addiction may be using diverted treatment drugs like buprenorphine to treat their own symptoms of withdrawal.²⁵ Studies have found that diverted buprenorphine is not likely to be misused but instead used to

²³ Christine Vestal, *At Rikers Island, a Legacy of Medication Assisted Opioid Treatment*, PEW: STATELINE (May 23, 2016), <https://www.pewtrusts.org/en/research-and-analysis/blogs/stateline/2016/05/23/at-rikers-island-a-legacy-of-medication-assisted-opioid-treatment>; Stephen Magura, *Buprenorphine and Methadone Maintenance in Jail and Post-Release: A Randomized Clinical Trial*, 99 DRUG ALCOHOL DEPENDENCE 222 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2658719/>.

²⁴ Surveys of individuals enrolled in outpatient therapy and community-based treatment programs indicate that those without access to legal prescriptions will seek out illicit methadone and buprenorphine. *See generally* Becky L. Genberg, et al., *Prevalence And Correlates Of Street-Obtained Buprenorphine Use Among Current And Former Injectors In Baltimore, Maryland*, 38 ADDICTION BEHAVIOR 2868 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3805723/>; Alexander R. Bazazi, *Illicit Use of Buprenorphine/Naloxone Among Injecting and Noninjecting Opioid Users*, 5 J. ADDICTION MED. 175 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3157053/>.

²⁵ Michelle R. Lofwall & Jennifer R. Havens, *Inability To Access Buprenorphine Treatment As A Risk Factor For Using Diverted Buprenorphine*, 126 DRUG ALCOHOL DEPENDENCE 379 (2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3449053/>.

self-medicate or to reduce withdrawal symptoms among people who do not have formal access to these medications.²⁶

II. FORCED WITHDRAWAL AND PROVISION OF DEPOT NALTREXONE IS NOT THE STANDARD OF CARE NOR DOES IT SAFELY TREAT OUD

A. “Detoxification” Is Not the Standard of Care for OUD

Defendants incorrectly claim that within the prison setting “detoxification” is the standard of care. Instead, many scientific and medical authorities,²⁷ as well as political bodies that have grappled with this issue, have stated that prisons should not require forced withdrawal and instead should provide MOUD, including access to methadone and buprenorphine when treating those with OUD. Both the bipartisan Presidential Commission on Combating Drug Addiction and the Opioid Crisis and the World Health Organization recommend the use of methadone and buprenorphine in incarcerated populations.²⁸ The American Correctional Association and the American Society for Addiction Medicine issued a joint statement supporting access to all three medications, including methadone, recommending:

All individuals who arrive into the correctional system who are undergoing opioid use disorder treatment should be evaluated for consideration to continue treatment within the jail or prison system. Individuals who enter the system and are currently on [MOUD] and/or psychosocial treatment should be considered for maintenance on that treatment protocol.²⁹

²⁶ Alexander R. Bazazi et al., *Illicit Use Of Buprenorphine/Naloxone Among Injecting And Noninjecting Opioid Users*, 5 J ADDICT MED. 175 (2011), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3157053/>.

²⁷ See U.S. FOOD & DRUG ADMIN., *Information About Medication-Assisted Treatment (MAT)* (Oct. 3, 2018), <https://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm600092.htm>; *Effective Treatments for Opioid Addiction*, NAT’L HEALTH INST., NAT’L INST ON DRUG ABUSE, <https://www.drugabuse.gov/publications/effective-treatments-opioid-addiction/effective-treatments-opioid-addiction>. (last visited Oct. 31, 2018); *Assessing and Addressing Opioid Use Disorder*, CTR. FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/drugoverdose/training/oud/accessible/> (last visited Oct. 31, 2018); WORLD HEALTH ORG., *supra* note 11; ASAM, *supra* note 12 at 29-31.

²⁸ PRESIDENT’S COMMISSION ON COMBATING DRUG ADDICTION AND THE OPIOID CRISIS, 72-73 (Nov. 2, 2017), https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf; WORLD HEALTH ORG., *supra* note 11.

²⁹ Press Release, American Correctional Association, Joint Public Correctional Policy On The Treatment Of Opioid Use Disorders For Justice Involved Individuals (Jan. 9, 2018) (on file at: https://www.asam.org/docs/default-source/public-policy-statements/2018-joint-public-correctional-policy-on-the-treatment-of-opioid-use-disorders-for-justice-involved-individuals.pdf?sfvrsn=26de41c2_2).

Although the Defendants emphasize the support SAMHSA has provided to their program, SAMHSA itself fully supports treatment with methadone. Contrary to the claims of the Defendants, SAMHSA states that methadone “allows people to recover from their addiction and to reclaim active and meaningful lives.”³⁰

B. Defendants Misstate the Effectiveness of Depot Naltrexone Relative to Other MOUDs

Depot naltrexone is FDA-approved for the treatment of OUD. However, this does not mean the medication is interchangeable with or as effective as methadone for all patients.³¹ Indeed, there is more evidence that methadone and buprenorphine effectively treat OUD than there is for depot naltrexone.³² Dozens of studies show that the use of methadone and buprenorphine decreases the use of illicit opioids, increases retention in treatment, and decreases mortality.³³ In contrast, extended-release injectable naltrexone is one of the newest, and as a result, least-studied interventions for opioid addiction. For example, there have yet to be studies that assess the impact of injectable naltrexone use on risk of death. A recent Massachusetts study of individuals who had a previous opioid overdose found a decrease in mortality after treatment with methadone or buprenorphine—but not after treatment by injectable naltrexone.³⁴

C. Defendants’ Withdrawal Management Program Does Not Actually Treat OUD

Defendants list a number of medications provided to inmates to assist with the discomfort of withdrawal. However, those medications assist with withdrawal management, and are not actual treatment for OUD. Simply providing withdrawal management is dangerous as it can lead

³⁰ *Methadone*, SUBSTANCE ABUSE & MENTAL HEALTH SERV. ADMIN. (Sept. 28, 2015) <https://www.samhsa.gov/medication-assisted-treatment/treatment/methadone>.

³¹ See U.S. FOOD & DRUG ADMIN., *supra* note 86.

³² Connery *supra* note 3.

³³ Connery, *supra* note 3; Larochelle, *supra* note 19; Sordo, *supra* note 6.

³⁴ Larochelle, *supra* note 19.

to a return of significant cravings and increase the risk of relapse substantially. Without appropriate attention, withdrawal can cause vomiting and diarrhea, leading to severe dehydration, hypernatremia (elevated sodium in blood), organ failure, and death.³⁵ Forcing people treated with methadone to experience withdrawal can lead some inmates to avoid restarting methadone treatment after release.³⁶

As indicated in the record, plaintiff asserts that the methadone treatment he is receiving is working; his OUD is under control and he has reengaged with his family and community. The Defendants' plan to stop the Plaintiff's methadone treatment, force withdrawal, and eventually provide depot naltrexone will place him at greater risk and is not appropriate care for his OUD.

CONCLUSION

Methadone is a safe and effective medication for the treatment of OUD, associated with a lower risk of overdose, lower risk of infectious disease, and lower risk of criminal behavior. Methadone treatment for OUD has the support of medical and scientific authorities around the world. There is no medical or scientific justification for stopping this effective medication, forcing withdrawal, and offering a medication with less evidence to support its use.

³⁵ Shane Darke et al., *Yes, People Can Die From Opiate Withdrawal*, 112 ADDICTION 199 (2016), <https://onlinelibrary.wiley.com/doi/epdf/10.1111/add.13512>; Maryclaire Dale, *Lebanon County Pays Nearly \$5M Over Withdrawal Death In Jail*, WITF. (Oct. 24, 2018, 12:31 PM), <http://www.witf.org/news/2018/10/lebanon-county-pays-nearly-5m-over-heroin-withdrawal-death-in-jail.php>.

³⁶ Shannon Gwin Mitchell et al., *Incarceration And Opioid Withdrawal: The Experiences Of Methadone Patients And Out-Of-Treatment Heroin Users*, 41 J. PSYCHOACTIVE DRUGS, 145 (2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2838492/>.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Amici certify that they have used both the Federal Rules of Appellate Procedure (Fed. R. App. P. 29(a)(5) and 32(a)(7)(B)) and Local Rule 7.1(b)(4) for reference and have, accordingly, limited their brief to fewer than ten pages and fewer than 6,500 words.

/s/ Mark MacDougall

CERTIFICATE OF SERVICE

I certify that on November 26, 2018, the foregoing Brief was electronically submitted to the Clerk of Court for the U.S. District Court for the District of Massachusetts using the Court's electronic case filing system. Accordingly, notice of this filing will be sent to all counsel of record.

/s/ Mark MacDougall